IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CHIESI USA, INC., CORNERSTONE BIOPHARMA, INC., and EKR THERAPEUTICS, LLC, Plaintiffs, v. EXELA PHARMA SCIENCES LLC, EXELA PHARMSCI, INC., and EXELA HOLDINGS, INC., Defendants.	Civil Action No. 1:13-cv-01275-GMS

DECLARATION OF ANGUS CHEN, ESQ. IN SUPPORT OF
PLAINTIFFS' OPENING CLAIM CONSTRUCTION BRIEF

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and EKR Therapeutics, LLC

I, ANGUS CHEN, ESQ., of full age, hereby certify as follows:

I am an attorney at law of the State of New York, where I am a member in good standing of the bar. I am a partner at the firm Frommer Lawrence & Haug LLP, 745 Fifth Avenue, New York, New York, 10151, and counsel for Plaintiffs Cornerstone Therapeutics Inc. (n/k/a Chiesi USA, Inc.), Cornerstone BioPharma, Inc., and EKR Therapeutics, LLC (collectively, "Chiesi" or "Plaintiffs").

I submit this declaration in support of Plaintiffs' Opening Claim Construction Brief.

1. Attached as Exhibit 1 is a true and correct copy of David W. Bates *et al.*, *Consensus Development Conference Statement on the Safety of Intravenous Drug Delivery Systems: Balancing Safety and Cost*, 35 Hospital Pharmacy 151 (2000) ("Bates").

2. Attached as Exhibit 2 is a true and correct copy of James Ruble, *Impact Safety, Efficiency, and the Bottom Line With Premixed IV Products*, Pharmacy Purchasing & Products (February 2008) ("Ruble").

3. Attached as Exhibit 3 is a true and correct copy of *Markman* Order, *Salix Pharms., Inc. v. Lupin Ltd.,* C.A. No. 1:12-cv-01104-GMS (D. Del., Dec. 17, 2013).

4. Attached as Exhibit 4 is a true and correct copy of portions of *Merriam Webster's Medical Desk Dictionary* (1996).

5. Attached as Exhibit 5 is a true and correct copy of Cardene® I.V. Premixed Injection Ordering Information, available at: http://www.cardeneiv.com/files/CardeneIV_Ordering_Info.pdf

6. Attached as Exhibit 6 is a true and correct copy of *Guidance for Industry: Q1A(R2) Stability Testing of New Drug Substances and Products*, Food and Drug Administration (November 2003).

7. Attached as Exhibit 7 is a true and correct copy of portions of Defendants' Supplemental New Drug Application, bates labeled EXELA0000150-172. **[Exhibit 7 is filed under seal.]**

8. Attached as Exhibit 8 is a true and correct copy of portions of the nonconfidential version of the Opening Claim Construction Brief filed by defendants Sandoz Inc., Sandoz AG, and ACS Dobfar Info S.A. ("Sandoz") in the related action *Chiesi USA, Inc., et al., v. Sandoz Inc., et al.*, CA No. 1:13-cv-05723-NLH-AMD (D.N.J. Nov. 26, 2014), ECF No. 211-1.

9. On January 19, 2015, Chiesi met and conferred with defendants Exela Pharma Sciences, LLC, Exela PharmSci, Inc., and Exela Holdings, Inc. (collectively "Exela" or "Defendants") pursuant to the Court's November 4, 2014 Order (ECF No. 41-1) to discuss narrowing and reducing the number of claim construction issues.

10. During the January 19, 2015 meet and confer, counsel for Exela asserted that a definition of the term "pre-mixed" that appears in column 11 of each patent in suit—"the term 'pre-mixed', as used herein, means a pharmaceutical composition that is already mixed from the point of manufacture and does not require dilution or further processing before administration"—is not a claimed "pre-mixed" embodiment. (*See, e.g.*, U.S. Patent No. 7,612,102, col.11, ll.25-29.)

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I hereby certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements are willfully false, I am subject to punishment.

Dated: February 20, 2015

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Angus Chen, Esq.